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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/424,487	02/29/2000	YEN CHOO	PM264975	8044	
20350 7	590 06/13/2003				
TOWNSEND AND TOWNSEND AND CREW, LLP			EXAMINER		
	TWO EMBARCADERO CENTER EIGHTH FLOOR			ROBINSON, HOPE A	
SAN FRANCISCO, CA 94111-3834			ART UNIT	PAPER NUMBER	
			1653	2/1	
			DATE MAILED: 06/13/2003	<i>55</i>	

Please find below and/or attached an Office communication concerning this application or proceeding.

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		Application No.	Applicant(s)
Office Action Summary		09/424,487	CHOO ET AL.
		Examin r	Art Unit
		Hope A. Robinson	1653
Period for	The MAILING DATE of this communication apport	pears on the cover sheet	with the correspondence address
A SH THE - Exte after - If th - If NO - Failu - Any	IORTENED STATUTORY PERIOD FOR REPL MAILING DATE OF THIS COMMUNICATION. ensions of time may be available under the provisions of 37 CFR 1.1 r SIX (6) MONTHS from the mailing date of this communication. e period for reply specified above is less than thirty (30) days, a repl of period for reply is specified above, the maximum statutory period are to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	I 36(a). In no event, however, may a sy within the statutory minimum of the will apply and will expire SIX (6) MC a, cause the application to become a	a reply be timely filed airty (30) days will be considered timely. DNTHS from the mailing date of this communication. ABANDONED (35 U.S.C. § 133).
1)⊠	Responsive to communication(s) filed on 21 I	March 2003 .	
2a)⊠	. , ,	nis action is non-final.	
3)□	Since this application is in condition for allowationsed in accordance with the practice under	ance except for formal m	
· _	ion of Claims	alla alla o	
4)[Claim(s) <u>1-30 and 32</u> is/are pending in the ap	•	
5\ <u>[</u>]	4a) Of the above claim(s) <u>25-30</u> is/are withdray	vn from consideration.	
· <u> </u>	Claim(s) is/are allowed.		
·	Claim(s) <u>1-24 and 32</u> is/are rejected. Claim(s) is/are objected to.		,
·	Claim(s) are subject to restriction and/o	r alaction requirement	
-	ion Papers	r election requirement.	
· · · ·	The specification is objected to by the Examine	r.	
•	The drawing(s) filed on is/are: a)□ accep		the Examiner.
	Applicant may not request that any objection to the	•	
11) 🔲	The proposed drawing correction filed on	is: a)☐ approved b)☐	disapproved by the Examiner.
	If approved, corrected drawings are required in rep	oly to this Office action.	
12)	The oath or declaration is objected to by the Ex	aminer.	
Priority ι	ınder 35 U.S.C. §§ 119 and 120		
13)⊠	Acknowledgment is made of a claim for foreign	n priority under 35 U.S.C.	§ 119(a)-(d) or (f).
a)[☐ All b)☐ Some * c)⊠ None of:		
	1. Certified copies of the priority documents	s have been received.	
	2. Certified copies of the priority documents	s have been received in A	Application No
* S	3. Copies of the certified copies of the prior application from the International Buse the attached detailed Office action for a list	reau (PCT Rule 17.2(a)).	Ç
	cknowledgment is made of a claim for domesti	•	
a) The translation of the foreign language pro Acknowledgment is made of a claim for domesti	visional application has b	peen received.
Attachmen			
2) 🔲 Notic	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of	Summary (PTO-413) Paper No(s) Informal Patent Application (PTO-152)
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DETAILED ACTION

- 1. Applicant's response to the Office Action mailed November 5, 2002 in Paper Nos. 32 and 35 on March 11, 2003 and April 10, 2003 is acknowledged. The Terminal Disclaimer filed March 21, 2003 has been received and entered.
- Claim 31 has been canceled. Claims 1-4, 14 and 15 have been amended. Claims
 1-30 and 32 are pending. Claims 1-24 and 32 are under examination.
- 3. The rejections under 35 U.S.C. 112, second paragraph and 103, Obvious Type Double Patenting have been withdrawn. The objection to the Information Disclosure Statement has been withdrawn as the references were found in the parent file 09/424,488; therefore, no new submission is necessary.
- 4. The following grounds of rejection are or remain applicable:

Restriction Requirement

5. Applicant maintains the traversal of the restriction requirement stating that the Choo et al. reference is not relevant to the claimed invention. Applicant's comments have been considered but are not persuasive. Paper No. 27 fully addressed the issues raised by applicant. Further, the Choo et al. reference is relevant to the claimed invention as stated below. Thus, the restriction requirement is proper and is final.

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Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-7, 9-11, 13, 15-23 and 32 remain rejected under 35 U.S.C. 102(b) as being anticipated by Choo et al. (WO 96/06166).

Choo et al. teaches rules for selecting amino acids within a-helixes of zinc fingers based on the nucleic acid sequence bound by the zinc finger. Choo et al. represents their nucleotide sequences in the traditional 5' to 3' direction using triplet nucleic acid codons. The instant invention represents the nucleotide sequence in complementary and 3' to 5' direction using the numbering of the originating 5' to 3' strand. Further, the instant application uses a quadruplet nucleic acid code, in which the 4th nucleotide of the quadruplet is the 1st nucleotide of the next quadruplet. Because of the difference in direction presentation, a schematic depiction of Choo et al. is provided of the nucleic acid sequence in the 5' to 3' direction and a comparison made of the same sequence as disclosed in the instant application. Note that Choo et al. refers to the first position of the triplet as the 5' position, the third as the 3' position, and second as the middle position in Table 2.

Choo et al: 1 2 3 1 2 3 1 2 3 1 2 3 -3' nt position

G G G A A A T T T C C C C

Due to the fact that one strand is 5' to 3' to the second strand which is 3' to 5', it is easy to flip the sequence of Choo et al. around and renumber as set forth in the instant invention (3' numbers). The flipped 5' numbers are also shown, for "book keeping" purposes. Because the reader gets to choose the quadruplet, the Examiner has numbered

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the claims using her own discretion and the Examiner's numbering will be the reference numbering for this rejection.

Instant claim 1(iib) states that if base 4 is C, then position +6 in the a-helix is Ser, Thr, Val, Ala, Glu or Asn. At page 25, Choo et al. teaches that cytosine cannot reliably discriminate by a hydrogen bonding amino acid side chain in the major groove; therefore, +6 in the a-helix can be any residue.

Instant claim 2(c) states that if nucleotide base 4 is G (position 1 of the 5' triplet), then position +6 in the a-helix is Arg or Lys. Table 2 on page 34 of Choo et al. teaches that when G is at position 5' of the triplet, then position +6 in the a-helix is Arg.

Instant claim 2(d) states that if nucleotide base 4 is T, then position +6 in the a-helix is Ser, Thr, Val or Lys. Table 2 on page 34 of Choo et al. teaches that when T is at position 5' of the triplet, then position +6 in the a-helix is Ser or Thr.

Instant claim 3(a) states that if nucleotide base 4 is G, then position +6 in the a-helix is Arg or Lys. Table 2 on page 34 of Choo et al. teaches that when G is at position 5' of the triplet, then position +6 in the a-helix is Arg.

Instant claim 3(b) states that if nucleotide base 4 is A, then position +6 in the a-helix is Glu, Asn or Val. At page 25, paragraph.1, Choo et al. states that "adenine is also an important determinant of sequence specificity, recognized almost exclusively by Asn or Gln... (when) A at the 5' end... the majority of which were of one clone with Asn at +6."

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Instant claim 3(c) states that if nucleotide base 4 is T, then position +6 in the a-helix is Ser, Thr, Val or Lys. Table 2 on page 34 of Choo et al. teaches that when T is at position 5' of the triplet, then position +6 in the a-helix is Ser or Thr.

Instant claim 3(d) states that if base 4 is C, then position +6 in the a-helix is Ser, Thr, Val, Ala, Glu or Asn. On page 25, para. 2, Choo et al. teaches that +6 in the a-helix can be any residue because cytosine cannot reliably discriminate by a hydrogen bonding amino acid side chain in the major groove.

Instant claim 3(e) states that if nucleotide base 3 is G (position 2 of the 5' triplet), then position +3 in the a-helix is His. Choo et al. teaches on Table 2 on page 34 that when G is placed in the middle or second position of the triplet, the +3 in the a-helix is His.

Instant claim 3(f) states that if base 3 is A, then position +3 of the a-helix is Asn.

Choo et al. teaches in Table 2 that when A is placed in the middle of the triplet, the +3 of the a-helix is Asn.

Instant claim 3(g) states that if base 3 is T, then position +3 of the a-helix is Ala, Ser or Val. Choo teaches in Table 2 that when T is placed in the middle of the triplet, the +3 in the a-helix is Ala, Ser or Val.

Instant claim 3(h) states that if base 3 is C, then position +3 of the a-helix is Ser, Asp, Glu, Leu, Thr or Val. Choo et al. teaches in Table 2 that when C is placed in the middle of the triplet, the +3 in the a-helix is Asp, Leu, Thr or Val.

Instant claim 3(i) states that if base 2 is G (position 3 or the 5' triplet), then position -1 of the a-helix is Arg. Choo et al. teaches in Table 2 that when T is placed at the 3' end or third position of the triplet, -1 of the a-helix is Arg.

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Instant claim 3(j) states that if base 2 is A, then position -1 of the a-helix is Gln. Choo et al. teaches in Table 2 that when A is placed at the 3' end of the triplet, -1 of the a-helix is Gln.

Instant claim 3(1) states that if base 2 is C, then position -1 of the a-helix is Asp or His. Choo et al. teaches in Table 2 that when C is placed at the 3' end of the triplet, -1 of the a-helix is Asp.

Instant claim 3(p) states that if base 1 is T, then position +2 of the a-helix is Ser or Thr. Choo et al. teaches in Table 2 that when T is placed at the 3' end of the triplet, +2 of the a-helix is Ser.

Regarding claim 4, Choo et al. teaches a zinc finger in which +4 is Leu and +7 is His- see Figure 2 wherein the sequence is as follows:

Regarding claim 5, Fig. 2 of Choo et al. teaches X^a as Phe or Tyr-X or ProPhe/Tyr-X.

Regarding claim 6, Fig. 2 of Choo et al. teaches X 2-4 as Arg-Ile.

Regarding claim 7, Fig. 2 of Choo et al. teaches X^b is Thr or Ile.

Regarding claim 9, Fig. 7 teaches that the linker is Thr-Gly-Glu-Lys or Thr-Gly-Glu-Lys-Pro.

Regarding claim 10, Fig. 2 of Choo et al. teaches that position +9 is Arg or Lys.

Regarding claim 11, sequence 1B of Fig. 7 shows that positions +1, +5, and +8 are not Phe, Trp or Tyr.

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Regarding claim 12, Fig. 7 shows that positions +1, +5, and +8 are not respectively occupied by the residues Lys, Thr and Gln

Regarding claim 13, Choo et al. in Table 1 teaches mutating zinc fingers.

Regarding claims 15 and 16, Choo et al. teaches (p. 6, paragraph 1) that the use of Zif268 as the model zinc finger.

Regarding claim 17, Fig. 13 of Choo et al. teaches two or more zinc finger motifs placed N to C terminal.

Regarding claim 18, Fig. 15 of Choo et al. teaches the N-terminal zinc finger is preceded by MAEEKP.

In Example 1, Choo et al. teaches the use of the phage display technique to build and screen a random zinc finger binding motif library. Thus, the methods of claims 19-21 are taught.

In Example 1, Choo et al. teaches that the fusions to the minor coat protein (pIII) of bacteriophage fd and the subsequent steps of the phage display assay. Thus claim 22 is taught. Also, Choo et al. teaches that positions –1, +3, +6 and +2 were randomized (p. 26, bottom and Fig. 2 as discussed in Example 1). Thus, claim 23 is anticipated.

Claim 32 is anticipated because while overlapping quadruplets are not expressly selected, the resulting triplets become the same because the numbering of base 4 and 1 are the same. Therefore, the limitations of the claims are met by this reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-7, 9-11, 13-23 and 32 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Choo et al. (WO 96/06166) in view of Krizek et al. (J. Am. Chem. Soc.; 1991; 113 (12); 4518-4523).

Choo et al. teaches rules for selecting amino acids within a-helixes of zinc fingers based on the nucleic acid sequence bound by the zinc finger. Choo et al. represents their nucleotide sequences in the traditional 5' to 3' direction using triplet nucleic acid codons. The instant invention represents the nucleotide sequence in complementary and 3' to 5' direction using the numbering of the originating 5' to 3' strand. Further, the instant application uses a quadruplet nucleic acid code, in which the 4th nucleotide of the quadruplet is the 1st nucleotide of the next quadruplet. Because of the difference in direction presentation, the Examiner will schematically depict Choo et al. nucleic acid sequence in the 5' to 3' direction and compare this same sequence to that disclosed so that the methods can be clearly discussed by reference to this figure. Note that Choo et al. refers to the first position of the triplet as the 5' position, the third as the 3' position, and second as the middle position in Table 2.

Choo et al: 1 2 3 1 2 3 1 2 3 1 2 3 -3' nt position

G G G A A A T T T C C C C

Due to the fact that one strand is 5' to 3' to the second strand which is 3' to 5', it is easy to flip the sequence of Choo et al. around and renumber as set forth in the instant invention (3' numbers). The flipped 5' numbers are also shown, for "book keeping"

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purposes. Because the reader gets to choose the quadruplet, the Examiner has numbered the claims using her own discretion and the Examiner's numbering will be the reference numbering for this rejection.

Instant claim 1iib states that if base 4 is C, then position +6 in the a-helix is Ser, Thr, Val, Ala, Glu or Asn. At page 25, Choo et al. teaches that cytosine cannot reliably discriminate by a hydrogen bonding amino acid side chain in the major groove; therefore, +6 in the a-helix can be any residue.

Instant claim 2c states that if nucleotide base 4 is G (position 1 of the 5' triplet), then position +6 in the a-helix is Arg or Lys. Table 2 on page 34 of Choo et al. teaches that when G is at position 5' of the triplet, then position +6 in the a-helix is Arg.

Instant claim 2d states that if nucleotide base 4 is T, then position +6 in the a-helix is Ser, Thr, Val or Lys. Table 2 on page 34 of Choo et al. teaches that when T is at position 5' of the triplet, then position +6 in the a-helix is Ser or Thr.

Instant claim 3a states that if nucleotide base 4 is G, then position +6 in the a-helix is Arg or Lys. Table 2 on page 34 of Choo et al. teaches that when G is at position 5' of the triplet, then position +6 in the a-helix is Arg.

Instant claim 3b states that if nucleotide base 4 is A, then position +6 in the a-helix is Glu, Asn or Val. At page 25, paragraph 1, Choo et al. states that "adenine is also an important determinant of sequence specificity, recognized almost exclusively by Asn

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or Gln... (when) A at the 5' end... the majority of which were of one clone with Asn at +6."

Instant claim 3c states that if nucleotide base 4 is T, then position +6 in the a-helix is Ser, Thr, Val or Lys. Table 2 on page 34 of Choo et al. teaches that when T is at position 5' of the triplet, then position +6 in the a-helix is Ser or Thr.

Instant claim 3d states that if base 4 is C, then position +6 in the a-helix is Ser, Thr, Val, Ala, Glu or Asn. On page 25, para. 2, Choo et al. teaches that +6 in the a-helix can be any residue because cytosine cannot reliably discriminate by a hydrogen bonding amino acid side chain in the major groove.

Instant claim 3e states that if nucleotide base 3 is G (position 2 of the 5' triplet), then position +3 in the a-helix is His. Choo et al. teaches on Table 2 on page 34 that when G is placed in the middle or second position of the triplet, the +3 in the a-helix is His.

Instant claim 3f states that if base 3 is A, then position +3 of the a-helix is Asn.

Choo et al. teaches in Table 2 that when A is placed in the middle of the triplet, the +3 of the a-helix is Asn.

Instant claim 3g states that if base 3 is T, then position +3 of the a-helix is Ala, Ser or Val. Choo et al. teaches in Table 2 that when T is placed in the middle of the triplet, the +3 in the a-helix is Ala, Ser or Val.

Instant claim 3h states that if base 3 is C, then position +3 of the a-helix is Ser, Asp, Glu, Leu, Thr or Val. Choo teaches in Table 2 that when C is placed in the middle of the triplet, the +3 in the a-helix is Asp, Leu, Thr or Val.

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Instant claim 3i states that if base 2 is G (position 3 or the 5' triplet), then position -1 of the a-helix is Arg. Choo et al. teaches in Table 2 that when T is placed at the 3' end or third position of the triplet, -1 of the a-helix is Arg.

Instant claim 3j states that if base 2 is A, then position -1 of the a-helix is Gln.

Choo et al. teaches in Table 2 that when A is placed at the 3' end of the triplet, -1 of the a-helix is Gln.

Instant claim 31 states that if base 2 is C, then position -1 of the a-helix is Asp or His. Choo teaches in Table 2 that when C is placed at the 3' end of the triplet, -1 of the a-helix is Asp.

Instant claim 3p states that if base 1 is T, then position +2 of the a-helix is Ser or Thr. Choo teaches in Table 2 that when T is placed at the 3' end of the triplet, +2 of the a-helix is Ser.

Regarding claim 4, Choo et al. teaches a zinc finger in which +4 is Leu and +7 is His- see Figure 2 wherein the sequence is as follows:

Regarding claim 5, Fig. 2 of Choo et al. teaches X^a as Phe or Tyr-X or ProPhe/Tyr-X.

Regarding claim 6, Fig. 2 of Choo et al. teaches X 2-4 as Arg-Ile.

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Regarding claim 9, Fig. 7 teaches that the linker is Thr-Gly-Glu-Lys or Thr-Gly-Glu-Lys-Pro.

Regarding claim 10, Fig. 2 of Choo et al. teaches that position +9 is Arg or Lys.

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Regarding claim 11, sequence 1B of Fig. 7 shows that positions +1, +5, and +8 are not Phe, Trp or Tyr.

Regarding claim 12, Fig. 7 shows that positions +1, +5, and +8 are not respectively occupied by the residues Lys, Thr and Gln

Regarding claim 13, Choo et al. in Table 1 teaches mutating zinc fingers.

Regarding claims 15 and 16, Choo et al. teaches (p. 6, paragraph 1) that the use of Zif268 as the model zinc finger.

Regarding claim 17, Fig. 13 of Choo et al. teaches two or more zinc finger motifs placed N to C terminal.

Regarding claim 18, Fig. 15 of Choo et al. teaches the N-terminal zinc finger is preceded by MAEEKP.

In Example 1, Choo et al. teaches the use of the phage display technique to build and screen a random zinc finger binding motif library. Thus, the methods of claims 19-21 are taught.

In Example 1, Choo et al. teaches that the fusions to the minor coat protein (pIII) of bacteriophage fd and the subsequent steps of the phage display assay. Thus claim 22 is taught. Also, Choo et al. teaches that positions –1, +3, +6 and +2 were randomized (p. 26, bottom and Fig. 2 as discussed in Example 1). Thus, claim 23 is anticipated.

Claim 32 is obvious because while overlapping quadruplets are not expressly selected, the resulting triplets become the same because the numbering of base 4 and 1 are the same.

Krizek teaches the peptide sequence described in SEQ ID NO:6 in the instant application. The peptide is described as a zinc finger peptide designed from a database of

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consensus sequences having the common formula of (Tyr, Phe)-X-Cys-X $_{2,4}$ -Cys-X $_{3}$ -Ohe-X $_{5}$ -Leu-X $_{2}$ -his-X $_{3,4}$. Krizak does not teach the set of rules of the method described in the instant application.

Choo et al. teaches the set of rules of the method described in the instant application (see above for the teachings of Choo et al.).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the sequence taught by Krizek as a model for zinc finger consensus structure and to have used the design logic to construct zinc finger consensus proteins. The person of ordinary skill in the art would have been motivated to use the above sequence as a model consensus peptide because the peptide is taught as such by Krizak. Thus, the claimed invention was within the ordinary skill in the art to make and use at the time of invention and was obvious.

8. The response filed on March 11, 2003 and April 10, 2003 has been considered but is not persuasive. Note that the rejections under 35 U.S.C. 102(b) and 103(a) remains. Regarding the rejection under 35 U.S.C. 102(b), the response on pages 14-17 states that applying the triplet rules of Choo et al. and the quadruplets rules of the instant application leads to different results. However, as stated above and in the schematic provided the triplet code of Choo et al. corresponds to the first three bases in the quadruplet code of the instant application and the fourth code of the quadruplet corresponds to the first base in the next series of codes. Moreover, the present application discloses an overlap between base 4 and the first base in the next set of codes. For example, if base 4 of the quadruplet is redefined as base 1 of the next triplet, then the

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results are the same. The examples provided by the applicant place a T in the position of base 4 and a G in position 1. Thus, when the triplet rules and the quadruplet rules are applied, the rules are essentially applied to different bases. However, if the triplet rules are applied to the example as if base 4 were renumbered to base 1 and thus represented by a T, the results are the same. Therefore, the applicant's arguments are found to be unpersuasive and the rejection has been maintained for the reasons stated above and in Paper No.27.

With regard to the rejection under 35 U.S.C. 103(a) as stated above in the discussion pertaining to the rejection under 35 U.S.C. 102(b) the Choo et al. reference is relevant to the claimed invention. The response on page 17 states that the Krizek reference does not remedy the lack of disclosure of the Choo et al. reference. However, this statement is not persuasive for the reasons set forth above, thus, the rejections remain.

Conclusion

9. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the

advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 6:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703) 308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS

Patent Examiner

CHRISTOPHER S. F. LOW SUPERVISORY PATENT EXAMINER